#### IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA

:

v. : CIV

CIVIL NO. 10-cv-5688

AMERICAN HEALTH CARE, INC., and

EDWARD LETKO

MICHAELL Dep. Clerk

### CONSENT ORDER FOR PERMANENT INJUNCTION BY

This Consent Order for Permanent Injunction (Consent Order) is entered into among the United States of America, acting through the United States Attorney's Office for the Eastern District of Pennsylvania and American Health Care, Inc. and Edward Letko (hereafter collectively referred to as "the Parties"), through their authorized representatives.

#### RECITALS

- A. American Health Care, Inc. is a New Jersey corporation with its principal place of business at 304 Park Avenue South, New York, New York. Edward Letko is the President of American Health Care, Inc. American Health Care, Inc. distributes medical devices, including diabetic test strips, throughout the United States.
- B. The United States filed an action in the United States District Court of the Eastern District of Pennsylvania captioned *United States v. American Health Care, Inc. and Edward Letko*, No. 10- (the Civil Action).
- C. The United States contends that it has certain civil claims against American

  Health Care, Inc. and Edward Letko arising from American Health Care, Inc.'s offering for sale

  diabetic test strips, beginning in or about November 2004 and continuing until in or about June

  2006, that were misbranded and/or distributed in a manner designed to mislead pharmacists



and/or consumers. Specifically, American Health Care, Inc. placed stickers and/or labels on boxes of diabetic strips, which stickers and/or labels obscured language on the boxes that limited the geographic locations where the boxes were to be sold (e.g., language that stated that the boxes were "Not for Sale in North America"), and then offered those boxes, with the stickers and/or labels, for sale. That conduct is referred to below as the Covered Conduct.

- D. This Consent Order is not an admission of liability by American Health Care, Inc. nor Edward Letko as to any allegation in the Complaint, nor is it a judgment of fraud; this Consent Order also is not a concession by the United States that its claims are not well founded.
- E. The Parties agree that, to avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Consent Order, the entry of the Consent Order is the most appropriate manner of resolving the claims alleged in the Civil Action.

NOW THEREFORE, before the taking of any testimony, without further adjudication or admission of any issue of fact or law, and upon consent of the Parties, it is hereby ORDERED, ADJUDGED and DECREED as follows:

#### TERMS AND CONDITIONS

1. American Health Care, Inc. and Edward Letko, for now and always, will refrain from altering any box of diabetic strips in such a way as to obscure material information on that box, including without limitation language on that box that limits the geographic locations where the box is to be sold (e.g., language that states that the box is "Not for Sale in North America"), and/or from knowingly purchasing such a materially altered box, and then offering that box for sale. American Health Care, Inc. and Edward Letko further waive any possessory or ownership interest they may have to any box of diabetic test strips seized during a February 15, 2005,



search of American Health Care, Inc.'s offices in New York.

- 2. Subject to the exceptions in Paragraph 3 (concerning excluded claims) below, the United States releases American Health Care, Inc. and Edward Letko from any civil claim the United States has for the Covered Conduct under the Fraud Injunction Statute, 18 U.S.C. § 1345.
- 3. Notwithstanding the release given in paragraph 2 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released by this Consent Decree: (1) any liability arising under Title 26, U.S. Code (Internal Revenue Code); (2) any criminal liability; (3) except as explicitly stated in this Consent Decree, any administrative liability; (4) any liability to the United States (or its agencies) for any conduct other than the Covered Conduct; (5) any liability based upon obligations created by this Consent Decree; (6) any claim arising under statute, law, or regulation other under 18 U.S.C. § 1345; and (7) any claim, right, or cause of action that could be brought by any person other than the United States.
- 4. American Health Care, Inc. and Edward Letko waive and shall not assert any defenses American Health Care, Inc. and Edward Letko may have to any administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Consent Decree bars a remedy sought in such administrative action. Nothing in this paragraph or any other provision of this Consent Decree constitutes an agreement by the United States concerning the characterization of the actions undertaken pursuant to the Consent Decree for purposes of the Internal Revenue laws, Title 26 of the United States Code.
  - 5. American Health Care, Inc. and Edward Letko fully and finally release the United



States, and its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that American Health Care, Inc. and Edward Letko have asserted, could have asserted, or may assert in the future against the United States, and its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

- 6. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Consent Decree.
- 7. Each party and signatory to this Consent Decree represents that it freely and voluntarily enters in to this Consent Decree without any degree of duress or compulsion.
- 8. This Consent Decree is governed by the laws of the United States. For purposes of construing this Consent Decree, this Consent Decree shall be deemed to have been drafted by all Parties to this Consent Decree and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.
- 9. This Court has jurisdiction over the subject matter of this action and over the Parties. Venue is proper in the Eastern District of Pennsylvania. For the purposes of this Consent Decree, or any action to enforce this Consent Decree, the Parties consent to the Court's jurisdiction over this Consent Decree and any such action and over the Parties and consent to venue in this judicial district. For the purposes of this Consent Decree, American Health Care, Inc. and Edward Letko agree not to contest the Complaint on the grounds that the Complaint does not state claims upon which relief can be granted. American Health Care, Inc. and Edward Letko agree to waive any rights they may otherwise have to raise timeliness as a defense to the Complaint or the allegations therein.
  - 10. This Consent Decree constitutes the complete agreement between the Parties.

This Consent Decree may not be amended except by written consent of the Parties or Order of this Court.

- 11. The undersigned represent and warrant that they are fully authorized to execute this Consent Decree on behalf of the persons and entities indicated below.
- 12. This Consent Decree may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.
- 13. This Consent Decree is binding on the successors, transferees, heirs, and assigns of America Health Care, Inc. and Edward Letko.
- 14. All parties consent to the United States' disclosure of this Consent Decree, and information about this Consent Decree, to the public.
- 15. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Consent Decree.
- 16. This Court shall retain jurisdiction over this matter to enforce or modify the Consent Decree or to resolve all disputes arising hereunder as may be necessary or appropriate for construction or execution of this Consent Decree.
- 17. Upon entry of this Consent Decree by this Court, this Consent Decree shall constitute a final judgment of the Court as to the Parties.

IT IS SO ORDERED

Dated and entered this \_\_\_\_\_ day of November 2010.







## THE UNITED STATES OF AMERICA

ZANE DAVID MEMEGER United States Attorney

MARGARET L. HUTCHINSON Assistant United States Attorney

DATED:

Chief, Civil Division

Assistant United States Attorney

DATED: Iche Lu

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# AMERICAN HEALTH CARE, INC. and EDWARD LETKO

FOR AMERICAN HEALTH CARE, INC.:

ARD LETKO

DATED: 10-11-10

DATED: 10/5/2013